

REMARKS

Entry of the foregoing and reconsideration of the application identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.114 and in light of the remarks which follow, are respectfully requested.

At the outset, Applicants note that entry and consideration of the Amendment Under 37 C.F.R. §1.116 filed on March 2, 2009, is respectfully requested in view of the Request for Continued Examination filed herewith.

Applicants thank Examiner Ellis and Examiner Woodward of the U.S. Patent and Trademark Office for their time and consideration in participating in an interview with Applicants' representative on April 10, 2009. During the interview, the Examiners advised that the rejections under 35 U.S.C. §112, first and second paragraphs, would be withdrawn. A proposed amendment to claim 14 was discussed, and the Examiners advised that they would consider withdrawing the art rejections upon submission of such claim amendment. In this regard, the Interview Summary dated April 10, 2009, accurately reflects the substance of the interview.

By the above amendments, claim 14 has been amended to recite that the polymer is in a hardened state. Support for such amendment can be found in the instant specification at least at paragraph [0055] of the published application. Claim 14 has been amended for readability purposes to recite "a blend of the polymers,". Support for newly added dependent claim 64 can be found at least at paragraphs [0032] and [0033] of the published application. Support for newly added dependent claim 65 can be found at least at paragraph [0030] of the published application. Entry of the above amendments is proper at least because a Request for Continued Examination is being filed herewith. See 37 C.F.R. §1.114.

In the Official Action, claims 14-43 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 14-43 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. During the interview, the Examiner agreed to withdraw the above §112 rejections, and such action is respectfully requested.

Claims 14-20, 23, 32, 33 and 38-43 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,645,503 (*Lin et al*) in view of U.S. Patent Application Publication No. US 2002/0016636 (*Ricci et al*). Claims 21, 22, 24, 25 and 28 stand rejected as being obvious over *Lin et al* in view of *Ricci et al*, and further in view of U.S. Patent No. 5,338,772 (*Bauer et al*). Claim 31 stands rejected as being obvious over *Lin et al* in view of *Ricci et al*, and further in view of U.S. Patent No. 4,610,692 (*Eitenmuller et al*). Withdrawal of these rejections is respectfully requested for at least the following reasons.

Independent claim 14 is directed to a biocompatible and biodegradable implant for filling a cavity in a living organism comprising polymer-coated biocompatible and biodegradable granules fused together through polymer linkage. Such claim recites that a major portion of the surface area of said granules is coated with at least one biocompatible and biodegradable layer of a polymer, wherein the polymer is in a hardened state.

As discussed during the interview, *Lin et al* relates to very low molecular weight materials that are in a soft, gummy state and act as excellent thermosensitive binders for the bone graft material. See col. 4, line 64 to col. 5, line 2. *Lin et al* discloses that "Unlike solid implants which have been used heretofore, implant rigidity is produced by tissue ingrowth and replacement of binder, and the binder itself only provides initial

cohesiveness and semi-rigidity." Col. 7, lines 28-32. In stark contrast, and as noted above, claim 14 recites that the polymer of the layer which coats a major portion of the surface area of the granules, is in a hardened state. *Lin et al* has no disclosure or suggestion of such layer of a polymer in a hardened state. Rather, in view of the above teachings of *Lin et al*, it is clear that the soft, gummy state is a critical aspect of the binder employed in the *Lin et al* implant. Simply put, it would not have been obvious to substitute the soft, gummy binder of *Lin et al* with a polymer in a hardened state, as presently claimed.

The secondary applied documents (i.e., *Ricci et al*, *Bauer et al* and *Eitenmuller et al*) fail to cure the above-described deficiencies of *Lin et al*. In this regard, even if the secondary applied documents would have been combined with *Lin et al* in the manner proposed by the Patent Office, it would not have been obvious to modify *Lin et al* to arrive at an implant in which a polymer of a layer coating a major portion of the surface area of the granules, is in a hardened state, as recited in claim 14.

For at least the above reasons, it is apparent that independent claim 14 is non-obvious over the applied art. Accordingly, withdrawal of the above §103(a) rejections is respectfully requested.

Claims 14-20, 23-25, 28, 30, 32-34 and 38-43 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,869,445 (*Johnson*) in view of *Lin et al* and further in view of *Ricci et al*. Claims 21 and 22 stand rejected as being obvious over *Johnson* in view of *Lin et al*, and further in view of *Ricci et al* and further in view of *Bauer et al*. Claims 26 and 27 stand rejected as being obvious over *Johnson* in view of *Lin et al* and further in view of *Ricci et al* and further in view of U.S. Patent No. 6,455,024 (*Glajch et al*). Claim 29 stands rejected as being obvious over *Johnson* in

view of *Lin et al* and further in view of *Ricci et al* and further in view of *Glajch et al*, and further in view of *Bauer et al*. Claim 31 stands rejected as being obvious over *Johnson* in view of *Lin et al* and further in view of *Ricci et al* and further in view of *Eitenmuller et al*. Claims 35-37 stand rejected as being obvious over *Johnson* in view of *Lin et al* and further in view of *Ricci et al* and further in view of U.S. Patent No. 3,918,968 (*Kukla et al*). Withdrawal of these rejections is respectfully requested for at least the following reasons.

As noted during the interview, *Johnson* relates to a fabric bag for insertion into an enlarged chamber between vertebrae. *Johnson* discloses placing a tube into an open mouth of the bag, and introducing beads into the bag. The addition of the beads causes the bag to expand into intimate contact with the walls of the chamber. See col. 7, lines 24-33. As noted during the interview, *Johnson* fails to disclose or suggest that the polymer of the layer which coats a major portion of the surface area of the granules, is in a hardened state, as recited in claim 14. There is simply no disclosure or suggestion of the use of such polymer in a hardened state.

The secondary applied documents (i.e., *Lin et al*, *Ricci et al*, *Bauer et al*, *Glajch et al*, *Eitenmuller et al* and *Kukla et al*) fail to cure the above-described deficiencies of *Johnson*. In this regard, even if the secondary applied documents would have been combined with *Johnson* in the manner proposed by the Patent Office, it would not have been obvious to modify *Johnson* to arrive at an implant wherein a polymer of a layer which coats a major portion of the surface area of the granules, is in a hardened state, as recited in claim 14.

For at least the above reasons, it is apparent that independent claim 14 is non-obvious over the applied documents. Accordingly, withdrawal of the above §103(a) rejections is respectfully requested.

Claim 14 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 36, 42 and 43 of copending Application No. 10/540,323. The Examiner is respectfully requested to hold this rejection in abeyance until the present application is deemed to otherwise be in condition for allowance.

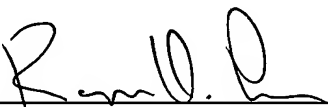
From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited. If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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